

§ 70.64

10 CFR Ch. I (1–1–11 Edition)

(iii) Facility hazards that could affect the safety of licensed materials and thus present an increased radiological risk;

(iv) Potential accident sequences caused by process deviations or other events internal to the facility and credible external events, including natural phenomena;

(v) The consequence and the likelihood of occurrence of each potential accident sequence identified pursuant to paragraph (c)(1)(iv) of this section, and the methods used to determine the consequences and likelihoods; and

(vi) Each item relied on for safety identified pursuant to § 70.61(e) of this subpart, the characteristics of its preventive, mitigative, or other safety function, and the assumptions and conditions under which the item is relied upon to support compliance with the performance requirements of § 70.61.

(2) Integrated safety analysis team qualifications. To assure the adequacy of the integrated safety analysis, the analysis must be performed by a team with expertise in engineering and process operations. The team shall include at least one person who has experience and knowledge specific to each process being evaluated, and persons who have experience in nuclear criticality safety, radiation safety, fire safety, and chemical process safety. One member of the team must be knowledgeable in the specific integrated safety analysis methodology being used.

(3) Requirements for existing licensees. Individuals holding an NRC license on September 18, 2000 shall, with regard to existing licensed activities:

(i) By April 18, 2001, submit for NRC approval, a plan that describes the integrated safety analysis approach that will be used, the processes that will be analyzed, and the schedule for completing the analysis of each process.

(ii) By October 18, 2004, or in accordance with the approved plan submitted under § 70.62(c)(3)(i), complete an integrated safety analysis, correct all unacceptable performance deficiencies, and submit, for NRC approval, an integrated safety analysis summary, including a description of the management measures, in accordance with § 70.65. The Commission may approve a request for an alternative schedule for

completing the correction of unacceptable performance deficiencies if the Commission determines that the alternative is warranted by consideration of the following:

(A) Adequate compensatory measures have been established;

(B) Whether it is technically feasible to complete the correction of the unacceptable performance deficiency within the allotted 4-year period;

(C) Other site-specific factors which the Commission may consider appropriate on a case-by-case basis and that are beyond the control of the licensee.

(iii) Pending the correction of unacceptable performance deficiencies identified during the conduct of the integrated safety analysis, the licensee shall implement appropriate compensatory measures to ensure adequate protection.

(d) *Management measures.* Each applicant or licensee shall establish management measures to ensure compliance with the performance requirements of § 70.61. The measures applied to a particular engineered or administrative control or control system may be graded commensurate with the reduction of the risk attributable to that control or control system. The management measures shall ensure that engineered and administrative controls and control systems that are identified as items relied on for safety pursuant to § 70.61(e) of this subpart are designed, implemented, and maintained, as necessary, to ensure they are available and reliable to perform their function when needed, to comply with the performance requirements of § 70.61 of this subpart.

§ 70.64 Requirements for new facilities or new processes at existing facilities.

(a) *Baseline design criteria.* Each prospective applicant or licensee shall address the following baseline design criteria in the design of new facilities. Each existing licensee shall address the following baseline design criteria in the design of new processes at existing facilities that require a license amendment under § 70.72. The baseline design criteria must be applied to the design of new facilities and new processes, but

do not require retrofits to existing facilities or existing processes (e.g., those housing or adjacent to the new process); however, all facilities and processes must comply with the performance requirements in § 70.61. Licensees shall maintain the application of these criteria unless the analysis performed pursuant to § 70.62(c) demonstrates that a given item is not relied on for safety or does not require adherence to the specified criteria.

(1) *Quality standards and records.* The design must be developed and implemented in accordance with management measures, to provide adequate assurance that items relied on for safety will be available and reliable to perform their function when needed. Appropriate records of these items must be maintained by or under the control of the licensee throughout the life of the facility.

(2) *Natural phenomena hazards.* The design must provide for adequate protection against natural phenomena with consideration of the most severe documented historical events for the site.

(3) *Fire protection.* The design must provide for adequate protection against fires and explosions.

(4) *Environmental and dynamic effects.* The design must provide for adequate protection from environmental conditions and dynamic effects associated with normal operations, maintenance, testing, and postulated accidents that could lead to loss of safety functions.

(5) *Chemical protection.* The design must provide for adequate protection against chemical risks produced from licensed material, facility conditions which affect the safety of licensed material, and hazardous chemicals produced from licensed material.

(6) *Emergency capability.* The design must provide for emergency capability to maintain control of:

- (i) Licensed material and hazardous chemicals produced from licensed material;
- (ii) Evacuation of on-site personnel; and
- (iii) Onsite emergency facilities and services that facilitate the use of available offsite services.

(7) *Utility services.* The design must provide for continued operation of essential utility services.

(8) *Inspection, testing, and maintenance.* The design of items relied on for safety must provide for adequate inspection, testing, and maintenance, to ensure their availability and reliability to perform their function when needed.

(9) *Criticality control.* The design must provide for criticality control including adherence to the double contingency principle.

(10) *Instrumentation and controls.* The design must provide for inclusion of instrumentation and control systems to monitor and control the behavior of items relied on for safety.

(b) Facility and system design and facility layout must be based on defense-in-depth practices.¹ The design must incorporate, to the extent practicable:

- (1) Preference for the selection of engineered controls over administrative controls to increase overall system reliability; and
- (2) Features that enhance safety by reducing challenges to items relied on for safety.

§ 70.65 Additional content of applications.

(a) In addition to the contents required by § 70.22, each application must include a description of the applicant's safety program established under § 70.62.

(b) The integrated safety analysis summary must be submitted with the license or renewal application (and amendment application as necessary),

¹As used in § 70.64, Requirements for new facilities or new processes at existing facilities, defense-in-depth practices means a design philosophy, applied from the outset and through completion of the design, that is based on providing successive levels of protection such that health and safety will not be wholly dependent upon any single element of the design, construction, maintenance, or operation of the facility. The net effect of incorporating defense-in-depth practices is a conservatively designed facility and system that will exhibit greater tolerance to failures and external challenges. The risk insights obtained through performance of the integrated safety analysis can be then used to supplement the final design by focusing attention on the prevention and mitigation of the higher-risk potential accidents.